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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,663	03/14/2002	Nelson D. Horseman	AVI021	2987
26739	7590	12/14/2005	EXAMINER	
AVIGENICS, INC. 111 RIVERBEND ROAD ATHENS, GA 30605			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/099,663

Applicant(s)

HORSEMAN ET AL.

Examiner

Celine X. Qian Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 108,110-133 and 135-151 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 108,110-133 and 135-151 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Claims 108, 110-133, 135-151 are pending in the application.

This Office Action is in response to the Amendment filed on 9/26/05.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/26/05 has been entered.

Response to Amendment

The rejection of claims 142-145 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 108, 110-133, 135-151 under 35 U.S.C. 112 1st paragraph is maintained for reasons set forth of the record mailed on 7/14/05 and further discussed below.

Claims 117 and 138 are rejected under 35 U.S.C. 102 (b) for reasons discussed below.

Claim 113 is rejected under 35 U.S.C. 112 2nd paragraph for reasons discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 117-133 and 135-151 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants assert the instant amendment obviates certain aspects of the examiner's rejection because it is limited to reciting the 0.5 kb promoter fragment which shows high promoter activity. Applicants further assert that an ordinary artisan would reasonably expect the 336 nucleotide fragment of SEQ ID NO:2, which is within the 0.5 kb fragment, to have gene controlling activity. Applicants argue that the upstream 300 nucleotides has been shown to be important in the gene expression in iFABP genes in other species such as rat and frog as disclosed by Rottman and Beck. Applicants thus conclude that the specification provides adequate description for the claimed invention.

The above arguments have been fully considered but deemed unpersuasive. The reasons that the claimed invention lack adequate description in the specification were discussed in detailed in the previous office action mailed on 7/14/05. In response to Applicant's arguments, Applicants are reminded that the claims are not limited to the 0.5 kb fragment of SEQ ID NO:1 that showed high promoter activity. For example, claim 117 read on any nucleic acid that hybridize to said fragment under moderate stringency condition, wherein the claimed genus of nucleic acid encompasses a large number of polynucleotides that share a low percent homology with the 0.5 kb fragment within SEQ ID NO:1. Since the specification does not teach what is essential sequence that is required for the gene controlling function, the structural-functional

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relationship is missing. Thus, the specification fail to provide adequate description for the claimed nucleic acid molecule.

With regard to Applicant's argument with regard to SEQ ID NO:2 having promoter activity, Applicants are reminded that having putative binding site within a sequence does not necessarily render the sequence having promoter activity. The art teaches that promoter region not only comprise transcriptional regulatory elements, but the other factors such as distance between those elements, secondary structure which affects the binding of the transcription factors are also important for the promoter function. Although the 0.5kb fragment comprising the fragment having the sequence of SEQ ID NO:2 has promoter activity, the fragment having sequence of SEQ ID NO:2 may not function as a proper promoter because the missing sequence may be necessary for the gene expression. Rottman and Gordon demonstrate there are important putative elements within -277 to -104 that are necessary of the promoter function, however, it does not teach whether the presence of said elements alone are sufficient for the promoter function. As such, the fact that SEQ ID NO:2 has same elements within the those present in -277 to -104 does not mean that SEQ ID NO:2 would have promoter function. Similarly, the demonstration of the rat iFABP promoter functions in frog by Beck does not mean that SEQ ID NO:2, a sequence comprises several elements conserved in the rat and frog iFABP, necessarily have promoter function. Absent evidence from the contrary, the specification fails to provide adequate description for sequences having SEQ ID NO:2 or homology with SEQ ID NO:2 and its complement for having "gene expression controlling" function.

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New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112

New Matter

Claims 108, 110-132 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 108, 110-132 introduces new limitation of "nucleotides 1115 to 1626 of SEQ ID O:1." Applicants assert that the support for this limitation can be found at page 7, line 5, which indicates where PCR primers hybridize to the 2381 bp sequence of SEQ ID NO:1. However, the legend of Figure 2 does not specifically indicate the nucleotide 1115-1626. A review of the Figure 2 itself does not reveal such information. While one can find out nucleotide 1115 is the start of the PCR primer, nucleotide 1626 is somewhere in the middle of the reverse primer. As such, there is no support for 1626. Therefore, the new limitation contains new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 113 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The recitation of “a sequence having at least 75% identity to SEQ ID NO:2” renders the claim indefinite because it is impossible to have a sequence share 90% homology to 1115-1626 of SEQ ID NO:1 and have 75% identity to SEQ ID NO:2, wherein SEQ ID NO:2 is within the 1115-1626 region. The nucleic acid sequence having 90% homology with the 0.5 kb fragment may have up to 52 bp difference, and the nucleic acid having 75% homology can have up to 95 bp difference, such sequence cannot satisfy both limitation. As such, the metes and bounds of the claim cannot be established.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 117 is rejected under 35 U.S.C. 102(b) as being anticipated by nucleic acid deposited as AC127531 (3/22/00).

Claim 117 is drawn to an isolated nucleic acid comprising a gene expression controlling region comprising a nucleic acid sequence that hybridizes under moderate stringency condition to a nucleic acid sequence of nucleotides 1115-1626 of SEQ ID NO:1, or its complement.

The nucleic acid deposited as AC1277531 share 49.2% homology 1115-1626 of SEQ ID NO:1. It would hybridize under moderate stringency to said sequence. Therefore, it anticipates the instantly claimed invention.

Claim 138 is rejected under 35 U.S.C. 102(b) as being anticipated by nucleic acid deposited as AU088319 (1/27/01).

Claim 138 is drawn to an isolated nucleic acid comprising a gene expression controlling region comprising a nucleic acid sequence that hybridizes under moderate stringency condition to a nucleic acid sequence SEQ ID NO:2, or its complement.

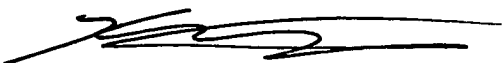
The nucleic acid deposited as AU088319 share 50.2% homology SEQ ID NO:2. It would hybridize under moderate stringency to said sequence. Therefore, it anticipates the instantly claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CELIAN QIAN
PATENT EXAMINER



Celine X Qian Ph.D.
Examiner
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